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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,751	12/21/2000	Mark N. Hochman	3486-018	1104

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GOTTLIEB RACKMAN & REISMAN PC
270 MADISON AVENUE
8TH FLOOR
NEW YORK, NY 100160601

EXAMINER	
HAYES, MICHAEL J	

ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/745,751	HOCHMAN, MARK N.	
	Examiner	Art Unit	
	Michael J. Hayes	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 April 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claims 14-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The new limitations added to the claims reciting a method of eliminating pain, eliminating pain-producing deflection, or preventing a needle from generating pain is new matter not originally disclosed in the specification as filed. The original specification mentions a method whereby "the amount of pain felt by the patient may be reduced." (abstract). This mention of a possibility to reduce pain does not provide a description of a method preventing or eliminating pain.

Claims 14-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's recitation of a method of eliminating pain, eliminating pain-producing deflection, or preventing a needle from generating pain is not enabled because Applicant has not provided a disclosure to enable one skilled in the art to use the method to provide painless needle deflection (or even reduced pain needle deflection) without undue experimentation. The claims

are broadly recited with limitations to advancing a needle with simultaneous rotation to prevent pain from needle deflection. There is no description of the amount of deflection to avoid in order to prevent pain from any remaining deflection. The state of the prior art does not provide information in providing painless needle advancement so this is not an instance of Applicant not teaching what is well known in the art. The level of predictability in the art is very low because the subject matter is subjective pain in biological systems. Applicant has not provided any direction or working examples concerning the elimination of pain in advancing needles with reduced deflection. The quantity of experimentation would be large because of the biological variability and subjective nature of pain measurements. Because of these factors the examiner concludes that the method of eliminating pain, eliminating pain-producing deflection, or preventing a needle from generating pain, as recited in the claims is not enabled.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 14, 15, 17, and 19, 22 are rejected under 35 U.S.C. 102(e) as being anticipated by BROWN (U.S. Patent No. 3,244,172). Brown discloses that it is well known in the art to turn or twist a beveled needle of a syringe while inserting it through tissue in methods of injecting.

(1:15-23). This method will inherently eliminate pain during the syringe insertion because it makes the insertion easier with less tissue affected by the insertion.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim Rejections - 35 USC § 103

Claims 14, 15, 17, 19, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over BROWN (U.S. Patent No. 3,244,172) in view of SPINELLO (US Patent No. 5,180,371). Brown discloses that it is well known in the art to turn or twist a beveled needle of a syringe while inserting it through tissue in methods of injecting (1:15-23). Brown shows a beveled needle in fig. 1. This method will inherently reduce or eliminate needle deflection and eliminate pain during the syringe insertion because it makes the insertion easier with less tissue affected by the insertion. Brown does not disclose injecting drugs while the needle is advanced and rotated or using an advancing rate of 2-4 mm/sec. Spinello teaches advancing a needle through tissue, including an advancing rate of 2-4 mm/sec (Spinello's disclosure of a rate less than 6 mm/sec includes the claimed range), and delivering drug while advancing the needle. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the

teachings of Spinello in the method disclosed as prior art in Brown in order to establish a range of volume over which the drug is administered and to reduce or eliminate pain as the needle is advanced (see col. 2, ll. 47-56).

Claims 18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over BROWN and SPINELLO as applied to claims 14 and 19 above, and further in view of KUHLE (US Patent No. 5,938,635). Brown and Spinello disclose that the insertion of a needle while rotating and delivering drug while advancing is known in the art. Brown and Spinello do not disclose rotating a needle up to 180 degrees in one direction during insertion to reduce deflection. Kuhle discloses a method of advancing a needle while rotating to reduce deflection of the needle. Kuhle teaches a rotation of 360 degrees to balance forces, or alternatively several rotations of 180 degrees while advancing the needle. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Kuhle in the method of Brown and Spinello to recognize the desirability for accurately placing drug delivery needles and the established practice of rotating a needle during insertion.

Claims 16 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over BROWN and SPINELLO and further in view of Garnier (US Patent No. 4381777). Brown and Spinello disclose the claimed invention except for rotating the needle in one direction, then the opposite direction as it is being advanced. Garnier teaches one directional and also bi-directional rotation (1:22-34). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Garnier in the method of Brown and Spinello in order to avoid injury or breakage. One of ordinary skill in the art would recognize the advantages of

Garnier's rotation in soft tissue because Garnier discloses rotation through the injection process which includes both soft tissue (i.e., porous bone) as well as harder bone.

Response to Arguments

Applicant's arguments with respect to claims 14-23 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments with respect to the rejections under 35 USC 112 are not convincing and the rejections are maintained above.

Applicant has not pointed to any location in the specification as filed that supports a method to eliminate pain by advancing a needle with only a small amount of bending. Applicant's citations on pgs 5-6 of remarks received 9/29/05 only discuss reduction of pain, not elimination of pain (i.e., painless).

Applicant has not provided any data to show that pain is eliminated or reduced when a needle is advanced with rotation. Applicant's parameters mentioned on pg. 7 of remarks received 9/29/05 concern the reduction of needle bending. There is no data given that correlates needle bending to quantitative amounts of pain. Without this correlation, one of ordinary skill in the art would not know how much bending is permitted to achieve the claimed method of reducing or eliminating pain. Additionally, since patients show different responses and tolerances to pain, lack of outward showing of pain does not mean the patient experienced a painless procedure, merely that the patient was able to tolerate the pain to a level below outward expression.

Applicant argues that exact parameters for practicing the method are not important (pgs. 7-8 of remarks received 9/29/05). Therefore it appears that complete lack of bending is not the object of the method, but rather a reduction in bending as compared to needle insertion without rotation.

Applicant's submitted declarations do not overcome the rejections because the declarations do not state that the practitioners measured a painless method (i.e., elimination of pain). In section 7 the practitioners merely state "reducing or eliminating" pain. This is quite different than a statement of eliminating pain in total, as recited in the claims. Furthermore, the declarations are merely opinion with regard to reducing or eliminating pain. The opinion appears to be based on a patient's outward show of discomfort or pain. However, a patient's tolerance to pain is not factored in and a patient does not always have an outward show of pain. The declarations do not establish data or facts that establish pain is reduced or eliminated with reduced bending of a needle while advanced into tissue. There is no data or facts established that correlate degree of needle bending to a degree (i.e., level) of pain.

Applicant argues that the prior art discloses needle rotation when it is to "enter" tissue, but that this does not mean needle rotation and advancement simultaneously in tissue. The examiner disagrees and interprets "enter" to mean advance in (i.e., move through) tissue.

Applicant argues that Kuhle is not relevant to the claimed method because it does not deal with pain management. The examiner disagrees because Kuhle addresses needle insertion in patients, which is the problem addressed in the claims. Kuhle teaches the claimed limitation of degrees of rotation and therefore teaches this aspect of the claimed invention. Applicant's

arguments concerning mode of operation between starting and ending positions are not recited in the claims.

Applicant argues that Garnier is not a needle for delivering anesthetic into a soft tissue, but such a delivery is not recited in the claims. The pain management of Garnier is found in its disclosure to prevent needle breakage while inserting a needle.

Applicant's arguments concerning a uniform, consistent advancing rate are irrelevant because such a uniform or consistent rate is not recited in the claims, nor described in the specification. Applicant's disclosure of an advancing rate of 2-4 mm/sec is not a description of a method of advancing a needle uniformly or consistently (i.e., at one constant rate from beginning to end of advancement).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (571) 272-4959. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons, can be contacted at (571) 272-4965. The fax number for submitting official papers is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

10 December 2005
mjh

MJ Hayes

MICHAEL J. HAYES
PRIMARY EXAMINER